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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/591,419	05/09/2008	Claus Frohberg	65084.000020	1422

21967 7590 09/26/2011
HUNTON & WILLIAMS LLP
INTELLECTUAL PROPERTY DEPARTMENT
2200 Pennsylvania Avenue, N.W.
WASHINGTON, DC 20037

EXAMINER

PAGE, BRENT T

ART UNIT	PAPER NUMBER
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1638

MAIL DATE	DELIVERY MODE
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09/26/2011

PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/591,419	FROHBERG ET AL.	
	Examiner	Art Unit	
	BRENT T. PAGE	1638	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 05 July 2011.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ An election was made by the applicant in response to a restriction requirement set forth during the interview on ____; the restriction requirement and election have been incorporated into this action.
- 4) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 5) ☒ Claim(s) 1 and 5-37 is/are pending in the application.
- 5a) Of the above claim(s) 9-18 and 26-35 is/are withdrawn from consideration.
- 6) ☒ Claim(s) 1,6-8,19-21 and 23-25 is/are allowed.
- 7) ☒ Claim(s) 5,22 and 37 is/are rejected.
- 8) ☒ Claim(s) 36 is/are objected to.
- 9) ☐ Claim(s) ____ are subject to restriction and/or election requirement.

Application Papers

- 10) ☐ The specification is objected to by the Examiner.
- 11) ☐ The drawing(s) filed on ____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
 Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
 Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 12) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. ____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|---|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. ____. |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date ____. | 6) <input type="checkbox"/> Other: ____. |

DETAILED ACTION

Applicants Reply filed on 07/05/2011 is hereby acknowledged. Claims 1, and 5-37 are pending. Claims 9-18 and 26-35 remain withdrawn as being drawn to non-elected subject matter. Claims 1, 5-8, 19-25 and 36-37 are examined herein on the merits. It is noted that the Examiner inadvertently left out claim 22 from the outstanding written description rejection, and therefore this action is being made non-final.

Claim Rejections - 35 USC § 102-withdrawn in part

Applicant's arguments, see pages 12-13, filed 07/05/2011, with respect to anticipation have been fully considered and are persuasive regarding the rejection of claim 5 when taken together with the claim amendments. The rejection of claim 5 under 35 USC 102(e) as being anticipated has been withdrawn.

Claim Rejections - 35 USC § 102

Claim 22 remains rejected and claim 37 is rejected under 35 U.S.C. 102(e) as being anticipated by Kikuchi et al (US20060123505, filed May 29, 2003).

The claims are drawn to any protein and any protein with alpha-1,4-glucan phosphorylating activity, respectively that may be identified by the instantly claimed method.

Kikuchi et al teach the transformation of a host cell and regeneration of a plant with SEQ ID NO:22133 which encodes the OK1 protein from rice. The resultant protein, inherently would be obtainable by the described methods.

Response to Arguments

Applicant's arguments filed 07/05/2011 have been fully considered but they are not persuasive.

Applicants urge that claims 5 and 22 are amended to require that the isolated protein comprises SEQ ID NO:5 and requires phosphorylated alpha-1,4 glucans as a substrate, respectively (see page 13 of response).

This is not persuasive because firstly, claim 22 does not require that the protein comprise SEQ ID NO:5, and secondly, the polypeptide taught by Kikuchi et al is identical to SEQ ID NO:4 with a single amino acid change. SEQ ID NO:4 is disclosed as being an OK1 protein isolated from rice. The disclosure does not indicate that this is a non-functional OK1 protein or that it does not require phosphorylated alpha-1,4 glucans as a substrate. The Examiner requests clarification as to whether SEQ ID NO:5 is a required feature of an OK1 protein, and further, whether SEQ ID NO:4 of the instant invention is considered to be an OK1 protein as the disclosure states, or whether it does not meet the criteria since it does not comprise SEQ ID NO:5. For Applicants convenience, the alignment is presented, below.

```
RESULT 5
AQD56650
ID    AQD56650 standard; protein; 1206 AA.
XX
AC    AQD56650;
XX
DT    12-JUN-2008    (first entry)
XX
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DE Rice cDNA-encoded protein SEQ ID No 50509.
XX
KW plant; transgenic plant; crop improvement.
XX
OS Oryza sativa.
XX
PN JP2005185101-A.
XX
PD 14-JUL-2005.
XX
PF 11-DEC-2002; 2002JP-00383870.
XX
PR 30-MAY-2002; 2002JP-00203269.
XX
PA (DOKU-) DOKURITSU GYOSEI HOJIN NOGYO SEIBUTSU SH.
PA (SEIB-) SEIBUTSUKEI TOKUTEI SANGYO GIJUTSU.
PA (DOKU-) DOKURITSU GYOSEI HOJIN RIKAGAKU KENKYUSH.
PA (KOKU-) ZH KOKUSAI KAGAKU SHINKO ZAIDAN.
XX
PI Kikuchi H, Hayashizaki Y, Otomo Y, Matsubara K, Murakami K;
PI Kishimoto N, Sato K, Nagata T, Kawakami N, Yazaki J, Ishikawa M;
PI Doi K, Kawai J;
XX
DR WPI; 2005-566181/58.
XX
PT Novel DNA encoding transcription factor, derived from rice plant, useful
PT for obtaining transcriptional-regulatory regions in plant and for
PT producing modified plant.
XX
PS Claim 1; SEQ ID NO 50509; 2928pp; Japanese.
XX
CC The present invention relates to Rice cDNA clones and to: DNA encoding
an
CC antisense RNA that is complementary to the transcription product of the
CC cDNA; a DNA encoding an RNA having ribozyme activity that cleaves
CC specifically the transcription product of the cDNA; DNA encoding an RNA
CC that suppresses the expression of cDNA through RNA interference effect
at
CC the time of the expression in a plant cell; or a DNA encoding RNA that
CC suppresses the expression of the cDNA through co-suppression effect at
CC the time of expression in a plant cell; a vector containing the cDNA or
CC DNA encoding a interference RNA; a transformed plant cell the vector; a
CC transformed plant the plant cell; an offspring, a clone or a
reproductive
CC fragment of the plant; a protein encoded by the cDNA; an antibody
binding
CC to the protein encoded by the cDNA; a rice-genome database containing a
CC cDNA or protein sequence of the invention; and a method for determining
CC transcriptional-regulatory regions by mapping a base sequence chosen
from
CC the cDNA sequences of the invention and determining the transcriptional-
CC regulatory region in the mapped region and in the 5'-terminal. The DNA
CC sequences, proteins, vectors, plants, antibodies, databases and methods
CC of the invention are useful for: producing the protein of the invention,

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CC for producing transgenic plants, for controlling the expression of a
gene
CC in a plant ,and for producing a modified plant with desired and
different
CC characteristics. The present sequence is a protein encoded by a cDNA
CC clone of the invention.
XX
SQ Sequence 1206 AA;

```

Query Match          99.8%;  Score 6145;  DB 2;  Length 1206;
Best Local Similarity 99.8%;
Matches 1204;  Conservative    1;  Mismatches    1;  Indels      0;  Gaps
0;

```

Qy 1 MTSLRPLETSLSIGGRPRRGLVLP PPGVGAGVLLRRGAMALPGRRGFACRGRSAASAAER 60

Db 1 MTSLRPLETSLSIGGRPRRGLVLP PPGVGAGVLLRRGAMALPGRRGFACRGRSAASAAER 60

Qy 61 TKEKKRRDSSKQPLVHLQVCL~~EHQVKFGEHVG~~IIGSTKELGSWEEQVELEWTTNGWVCQL
120

Db 61 TKEKKRRDSSKQPLVHLQVCL^{EHQ}VKFG^{EHV}GIIGSTKELGSWEEQVELEWTTNGWVCQL
120

Qy 121 KLPGETLVEFKFVIFLVGGKDKIWEDGNNRVVELPKDGKFDIVCHWNRTTEPLELLGTPK
180

Db 121 KLPGETLVEFKFVIFLVGGKDKIWEDGNNRVVELPKDGKFDIVCHWNRTTEPLELLGTPK
180

QY 181 FELVGAEKNTGEDASASVTFAPKVKQDISVVENGDPAPKAESSKFGGQWQGSKTVMRS
240

Db 181 FELVGAEKNTGEDASASVTFAPKQDISVVENGDPAPAEAPSKFGGQWQGSKTVMRS
240

Qy 241 NEHLNKEADRMWDTTGLDGI~~AL~~KLVEGDKASRNWWRKLEVV~~RG~~ILSESFDDQ~~S~~R~~L~~GALVY
300

Db 241 NEHLNKEADRMWDTTGLDGI~~AL~~KLVEGDKASRNWWRKLEVV~~RG~~ILSESFDDQ~~S~~R~~L~~GA~~L~~VY
300

QY 301 SAIYLKWIYTGQISCFEDGGHHRPNKHAEISRQIFRELEMMYYGKTTSAKDVLVIRKIH
360

Db 301 SAIYLKWIYTGQISCFEDGGHHRPNKHAEISRQIFRELEMMYYGKTTSAKDVLVIRKIHP
360

Qy 361 FLPSFKSEFTASVPLTRIRDIAHRNDIPHDLKQEIKHTIQNKLHRNAGPEDLIATEVMLA
420

Db 361 FLPSFKSEFTASVPLTRIRDIAHRNDIPHDLKQEI~~KHTIQ~~NKLHRNAGPEDLIATEVMLA
420

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Qy 421 RITKTPGEYSETFVEQFTIFYSELKDDFNAGSLFEQLESIKESLNEGLEVLSSFVETKR
480
Db 421 RITKTPGEYSETFVEQFTIFYSELKDDFNAGSLFEQLESIKESLNEGLEVLSSFVETKR
480

Qy 481 SLDQVDHAEDLDKNDTIQILMTTLQSLSSLRSVLMKGLESGLRNDAPDNAIAMRQKWRLC
540
Db 481 SLDQVDHAEDLDKNDTIQILMTTLQSLSSLRSVLMKGLESGLRNDAPDNAIAMRQKWRLC
540

Qy 541 EISLEDYSFVLLSRFINTLEALGGSASLAKDVARNTTLWDTTLDALVIGINQVVSFGWKT
600
Db 541 EISLEDYSFVLLSRFINTLEALGGSASLAKDVARSTTLWDTTLDALVIGINQVVSFGWKT
600

Qy 601 DECIAIGNEILSWKQKGLSESEGCEDGKYIWSLRLKATLDRARRLTEEYSEALLSIFPEK
660
Db 601 DECIAIGNEILSWKQKGLSESEGCEDGKYIWSLRLKATLDRARRLTEEYSEALLSIFPEK
660

Qy 661 VMVIGKALGIPDNSVRITYTEAEIRAGIVFQVSKLCTVLQKAIREVLGSGWDVLVPGVAH
720
Db 661 VMVIGKALGIPDNSVRITYTEAEIRAGIVFQVSKLCTVLQKAIREVLGSGWDVLVPGVAH
720

Qy 721 GTLMRVERILPGSLPSSVKEPVVLIVDKADGDEEVKAAGDNIVGVILLQELPHLSHLGVR
780
Db 721 GTLMRVERILPGSLPSSVKEPVVLIVDKADGDEEVKAAGDNIVGVILLQELPHLSHLGVR
780

Qy 781 ARQENVVFTCEYDDTVTDVYLLEGKYIRLEASSINVNLSIVSEKNDNAVSTEPNSTGNP
840
Db 781 ARQENVVFTCEYDDTVTDVYLLEGKYIRLEASSINVNLSIVSEKNDNAVSTEPNSTGNP
840

Qy 841 FQOKLQNEFSLPSDIEMPLQMSKQKSKSGVNGSFAALELSEASVESAGAKAAACRTLSVL
900
Db 841 FQOKLQNEFSLPSDIEMPLQMSKQKSKSGVNGSFAALELSEASVESAGAKAAACRTLSVL
900

Qy 901 ASLSNKVYSDQGVPAAFRVPSGAVIPFGSMEDALKKSGSLESFTSLLEKIETAKVENGEV
960
Db 901 ASLSNKVYSDQGVPAAFRVPSGAVIPFGSMEDALKKSGSLESFTSLLEKIETAKVENGEV
960

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Qy	961	DSLALQLQAIISHLSPPEETIIFLKRIFPQDVRLIVRSSANVEDLAGMSAAGLYDSIPNV
1020		
Db	961	DSLALQLQAIISHLSPPEETIIFLKRIFPQDVRLIVRSSANVEDLAGMSAAGLYDSIPNV
1020		
Qy	1021	SLMDPCAFAAGVGVWASLYTRRAILSRRAAGVYQRDATMAVLVQEILQPDLSFVLHTVC
1080		
Db	1021	SLMDPCAFAAGVGVWASLYTRRAILSRRAAGVYQRDATMAVLVQEILQPDLSFVLHTVC
1080		
Qy	1081	PADHDPKVVQAEVAPGLGETLASGTRGTPWRLSCNKFDGKVATLAFSNFSEEMVVHNSGP
1140		
Db	1081	PADHDPKVVQAEVAPGLGETLASGTRGTPWRLSCNKFDGKVATLAFSNFSEEMVVHNSGP
1140		
Qy	1141	ANGEVIRLTVDYSSKPLSVDTTFRKQFGQRLAAIGQYLEQKFGSAQDVEGCLVGKDIFIV
1200		
Db	1141	ANGEVIRLTVDYSSKPLSVDTTFRKQFGQRLAAIGQYLEQKFGSAQDVEGCLVGKDIFIV
1200		
Qy	1201	QSRPQP 1206
Db	1201	QSRPQP 1206

Claim Rejections - 35 USC § 112-enablement

Applicant's arguments, see page 12, filed 07/05/2011, with respect to enablement have been fully considered and are persuasive when taken together with the claim amendments. The rejection of claim 5 has been withdrawn.

Claim Rejections - 35 USC § 112-written description

The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claim 5 remains rejected and claims 22 and 37 are rejected under 35

U.S.C. 112, first paragraph, as failing to comply with the written description requirement.

The claims contain subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventors, at the time the application was filed, had possession of the claimed invention.

The claim is drawn to any OK1 protein obtainable by the method of claim 1 comprising a phosphohistidine domain or any OK1 protein at all. The specification only describes full length OK1 proteins from specific species, and does not describe any other variants, or species with proteins that bind preferentially to phosphorylated alpha-glucans, nor does the specification describe what features of the OK1 protein are required for this preferential binding.

As currently described, there are literally millions of OK1 proteins given the number of plant species, and it is not clear what polypeptide sequences will be required to be conserved in order to retain the function of an OK1 protein. The only working examples involve OK1 proteins from rice, Arabidopsis, wheat, barley, potato or millet, full-length proteins out of a genus that encompasses literally millions of proteins and

isoforms of proteins. Consequently, the instant specification does not describe a representative number of working examples for this extremely large genus.

In the absence of a representative number of working examples, the specification is required to at least describe the structural features that are required for function (ie preferentially binding phosphorylated alpha-glucans) by way sequence structure responsible for said function. The specification does not describe which sequences are absolutely required for this function or are likely to be conserved across proteins with a different function.

The Federal Circuit has recently clarified the application of the written description requirement. The court stated that a written description of an invention “requires a precise definition, such as by structure, formula, [or] chemical name, of the claimed subject matter sufficient to distinguish it from other materials.” *University of California v. Eli Lilly and Co.*, 119 F.3d 1559, 1568; 43 USPQ2d 1398, 1406 (Fed. Cir. 1997). The court also concluded that “naming a type of material generally known to exist, in the absence of knowledge as to what that material consists of, is not a description of that material.” *Id.* Further, the court held that to adequately describe a claimed genus, Patent Owner must describe a representative number of the species of the claimed genus, and that one of skill in the art should be able to “visualize or recognize the identity of the members of the genus.” *Id.*

Finally, the court held:

A description of a genus of cDNAs may be achieved by means of a recitation of a representative number of cDNAs, defined by nucleotide sequence, falling within the scope of the genus or a recitation of structural features common to members of the genus, which features constitute a substantial portion of the genus. *Id.*

See also MPEP section 2163, page 174 of chapter 2100 of the August 2005 version, column 1, bottom paragraph, where it is taught that

[T]he claimed invention as a whole may not be adequately described where an invention is described solely in terms of a method of its making coupled with its function and there is no described or art-recognized correlation or relationship between the structure of the invention and its function. A biomolecule sequence described only by a functional characteristic, without any known or disclosed correlation between that function and the structure of the sequence, normally is not a sufficient identifying characteristic for written description purposes, even when accompanied by a method of obtaining the claimed sequence.

See also *Amgen Inc. v. Chugai Pharmaceutical Co. Ltd.*, 18 USPQ 2d 1016 at 1021, (Fed. Cir. 1991) where it is taught that a gene is not reduced to practice until the inventor can define it by "its physical or chemical properties" (e.g. a DNA sequence).

Given the claim breadth and lack of description as discussed above, the specification fails to provide an adequate written description of the genus of sequences as broadly claimed. Given the lack of written description of the claimed genus of sequences, any method of using them, such as transforming plant cells and plants therewith, and the resultant products including the claimed transformed plant cells and plants containing the genus of sequences, would also be inadequately described. Accordingly, one skilled in the art would not have recognized Applicant to have been in possession of the claimed invention at the time of filing. See the Written Description Requirement guidelines published in Federal Register/ Vol. 66, No. 4/ Friday January 5, 2001/ Notices: pp. 1099-1111.

Response to Arguments

Applicant's arguments filed 07/05/2011 have been fully considered but they are not persuasive.

Applicants urge that the claims have been amended to recite the protein is an OK1 protein and comprises SEQ ID NO:5 (see page 12 of response).

This is not persuasive, because although the amendment does narrow the claim, the claim is still drawn to literally any OK1 polypeptide from any species. The specification simply does not describe the sequence features that must be retained in order to retain the function of an OK1 protein.

Claims 1, 6-8, 19-21, 23-25 and 36 appear to be free of the prior art given the failure of the prior art to teach or reasonably suggest a method of identifying a protein wherein the unknown protein is bound to both phosphorylated and non-phosphorylated alpha-1,4-glucans and isolated based on an increase binding to phosphorylated alpha-1,4-glucans. The closest prior art appears to be Lorbeth et al (1996 Nature Biotechnology 16:473-477). However, Lorbeth et al do not measure the proteins that bind preferentially to phosphorylated alpha-1,4-glucan, but rather, measure the phosphorous content of starch bound to protein. It is also noted that the method of Lorbeth et al does not involve the dissolving of proteins not bound to the starch and the isolation of the protein on that basis. Thus, claims 1, 6-8, 19-21 and 23-25 appear to be allowable subject matter.

Claim 36 is objected to for depending from a rejected claim but would be allowable if rewritten in independent form.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to BRENT T. PAGE whose telephone number is (571)272-5914. The examiner can normally be reached on Monday-Friday 8-5.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Anne Marie Grunberg can be reached on (571)-272-0975. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

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